

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference OP020135	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/KR2002/002427	International filing date (day/month/year) 24 DECEMBER 2002 (24.12.2002)	Priority date (day/month/year) 08 APRIL 2002 (08.04.2002)
International Patent Classification (IPC) or national classification and IPC IPC7 G01N 33/574		
Applicant BIOINFRA INC. et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 06 NOVEMBER 2003 (06.11.2003)	Date of completion of this report 29 JULY 2004 (29.07.2004)
Name and mailing address of the IPEA/KR Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer SHIN, Weon Hye Telephone No. 82-42-481-8155

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/KR2002/002427

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed
- ☒ the description:
 pages 1-24, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☒ the claims:
 pages 25-29, as originally filed
 pages _____, as amended (together with any statement) under Article 19
 pages 30, filed with the demand
 pages _____, filed with the letter of 18/06/2004
- ☐ the drawings:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____
- ☐ the sequence listing part of the description:
 pages _____, as originally filed
 pages _____, filed with the demand
 pages _____, filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language English which is

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☒ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☒ the claims, Nos. 22
- ☐ the drawings, sheet _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed," and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.

INTERNATIONAL PRELIMINARY EXAMINATION

International application No.

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-21	
	Claims		YES
Inventive step (IS)	Claims	1-21	
	Claims		YES
Industrial applicability (IA)	Claims	1-21	
	Claims		YES
			NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following document from the International Search Report (ISR).
D1: KR 2000-0052802 (patent family member: EP 934409)

1. Novelty & Inventive step

Objects of the present invention are to provide a system (claims 1-11) and a method (claims 12-20) for detection of cancer, by generating a serum proteome standard by an image mining technique, and to provide biomarkers specific to breast cancer (claim 21). The present invention (claims 1 & 12) comprises input means/step for inputting serum proteome; proteome standard production means/step; proteome comparison means/step; disease analysis means/step; and output means/step.

D1 is considered to represent the most relevant state of the art for the subject matter of present invention with respect to identifying and characterizing changes in proteomes by a computer-based system, which aligns a new proteome image with the master composite image that is corresponding to the proteome standard of the present invention. It relates to methods and computer systems for analyzing cell proteomes to characterize proteins that are up- or down-regulated under different conditions, such as under abnormal(diseased) or compound-treated conditions.

- Continued in Supplemental Box

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Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box V

However, the subject matters of claims 1 & 12 of the present invention are different from what D1 discloses in that an image mining technique is introduced to the proteome analyses of the present invention, wherein the proteome standard is generated by an image mining tool, which employs a genetic algorithm, a support vector machine, and a fuzzy rule-based classification means is also used for analysis and prognosis of disease states. None of the available documents, either alone or in combination, discloses such an introduction of an image mining technique to proteome analysis, which appears non-obvious to a person skilled in the art.

Claims 2-11 and claims 13-20 are dependent on claim 1 and claim 12, respectively. Therefore, the system to which claims 1-11 relate and the method to which claims 12-20 do are believed to be novel and to involve an inventive step as compared with prior arts fulfilling the requirements set forth in Article 33(2)&(3) PCT.

The subject matter of claim 21 is biomarkers comprising a novel proteome pattern specific to diagnosis of breast cancer, which has been generated by the method of the present invention. Claim 21 thus complies with the requirements set forth in Article 33(2)&(3) PCT.

2. Industrial applicability

Present invention relates to a computer-based system, a method and biomarkers for detection of cancer. There is no reason to negate the industrial applicability of this invention. Consequently, claims 1-21 appear to meet the requirements of Article 33(4) PCT.

Fuzzy technique; and

a rule-based classification step of arranging and normalizing the results obtained at the data mapping step, and thus generating a final rule base.

5 21. (amended) A biomarker or biomarkers for diagnosis of breast cancers, comprising a proteome pattern, wherein said proteome pattern is one or more selected from spots listed in Table 1.

22. (deleted)